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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,745	06/30/2000	Andrew Lawrence Darrow	ORT1273	8702

7590 06/12/2003

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EXAMINER

SWOPE, SHERIDAN

ART UNIT PAPER NUMBER

1652

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Sandra Puckett

215-568-3439

Office Action Summary	Application No.	Applicant(s)	
	09/861,925	POOLE ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, 15, drawn to nucleic acid molecules encoding proteases, classified in class 435, subclass 226.
- II. Claims 12, 13, drawn to protease polypeptides, classified in class 435, subclass 226.
- III. Claim 14, drawn to antibodies, classified in class 530, subclass 387.9.
- IV. Claims 16-18, drawn to methods for testing modulation of proteolytic activity by compounds, classified in class 435, subclass 23.
- V. Claims 19, 20, and 22, drawn to agonists or antagonists of a protease.

Classification unknown as the specification discloses no structural information for the claimed compound. Possible classification could be class 260 (organic compounds), class 530 (proteins), class 536 (carbohydrates), class 423 (inorganic compounds) etc.
- VI. Claim 21, drawn to modulators of protease expression. Classification unknown as the specification discloses no structural information for the claimed compound.

Possible classification could be class 260 (organic compounds), class 530 (proteins), class 536 (carbohydrates), class 423 (inorganic compounds) etc.
- VII. Claim 23, drawn to methods of treating a patient, classified in class 514, subclass 789.

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Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

Inventions I and III-VI are unrelated because the products of Inventions I and III-VI are physically and functionally distinct chemical entities.

Invention II is unrelated to Inventions III-V because the products of Invention I are physically and functionally distinct chemical entities from the products of Inventions III-VI.

The nucleic acids of Invention I are related to the proteins of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells, as recited in Claim 15. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The methods of Inventions IV and VII are unrelated because they comprise different steps, utilize different products and/or produce different results.

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The methods of Invention IV is unrelated to the products of Inventions I, III, and VI because, the methods of Invention IV can neither use the products of Inventions I, III, and VI nor be used to make said products.

The methods of Invention IV are related to the products of Inventions II and V as product and process of use. However, the methods of Invention IV are distinct from the products of Inventions II and V because the proteins of Invention II can also be used for production of an antibody while, the modulators of Invention V can also be used as pharmacological reagents and to purify the target enzyme.

The methods of Invention VII is unrelated to the products of Inventions I, II, III, and VI because, the methods of Invention VII can neither use the products of Inventions I, II, III, and VI nor be used to make said products.

The methods of Invention VII are related to the products of Invention V as product and process of use. However, the methods of Invention VII are distinct from the products of Inventions V because the modulators of Invention V can also be used to purify the target enzyme.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 9:30-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.


REBECCA E. PROUTY
PRIMARY EXAMINER
CROSS 1804
6/20